

8 c. a control system coupled to the laser source for controlling generation of the laser
9 pulses from the laser source, wherein the laser source operates in both an ablation
10 mode and a coagulation mode such that when in the ablation mode, the strength
11 and duration of the laser pulses are sufficient to ablate tissue at the area of tissue
12 being treated to a controllable ablation depth and when in the coagulation mode,
13 the strength and duration of the laser pulses are sufficient to generate a
14 coagulation region having a controllable coagulation depth within the tissue
remaining at the area of tissue being treated without ablating any tissue.

1 23. (Twice Amended) The medical laser delivery apparatus as claimed in claim 22
2 wherein [at least one of] the two or more lasers [is an] are erbium lasers.

1 24. (Twice Amended) The medical laser delivery apparatus as claimed in claim [22] 23
2 wherein the erbium lasers [is an] are Er:YAG lasers.

REMARKS

To further advance the prosecution of the instant application in view of a Final Office
Action and to place the Claims in better form for allowance the applicants submits the above
5 amendments.

The applicants respectfully appeal for further examination and reconsideration in view of
the above amendment and the remarks set forth below.

Prior to this amendment, Claims 1-14 and 17-24 were pending. Within the Office Action,
Claims 1-14 and 17-24 have been rejected. Claims 1, 8-11, 17, 23 and 24 have been amended.
10 Accordingly, Claims 1-14 and 17-24 are still pending.

Rejections Under 35 U.S.C. § 103

Within the Office Action, Claims 1-3, 6-8, 11-14 and 17-19 are rejected under 35 U.S.C.
§ 103(a) as being unpatentable over U.S. Patent No. 5,098,426 to Sklar et al. (hereinafter "Sklar")
15 in combination with U.S. Patent No. 4,672,969 to Dew (hereinafter "Dew"), U.S. Patent No.
5,620,435 to Belkin et al. (hereinafter "Belkin") and the article entitled "Selective

Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation" by R. Rox Anderson and John A. Parrish (hereinafter "Anderson").

The teachings of Sklar are applied as the primary reference in a U.S.C. 103(a) rejection of Claims 1-3, 6-8, 11-14, and 17-19 in the instant application. The reference to Sklar is not considered by the applicants to be analogous art for the reasons stated below. The teachings of Sklar are directed to a system and method for accurately controlling and positioning laser sources, specifically during surgery. The current invention is directed to a laser delivery apparatus for delivering one or more pulses to an area of tissue to be treated and generating a region of *coagulation to a controllable coagulation* depth under a surface of the area of tissue and the configuration of the laser source used to accomplish controllable coagulation.

According to Sklar "a limiting factor to the duration of the operation under these procedures (viz. Prior Art procedures) is the surgeon's reaction time while focusing on the target and the patients movement while the surgeon is trying to find the target and react to the target recognition by firing the laser. [Sklar, column 5, lines 13-19] In view of these prior art limitations, Sklar teaches a system for performing precision laser surgery which includes an imaging system for providing a surgeon with precision tracking and topographical information regarding the surgical target area. [Sklar, Abstract] Sklar states that "it is well appreciated that the limitations on the achievable accuracy and control of laser surgical instruments today is no longer paced by the development of laser technology, but by the imaging and tracking technologies needed to efficiently use the laser." [Sklar, column 2, lines 39-43] Therefore, the entire teachings of Sklar are directed to laser tracking and not a laser delivery system in accordance with the teachings of the present Application. Even if the teachings of Sklar in combination with the teachings of Dew, Belkin and Anderson were appropriate, Sklar fails to teach the dual mode laser source comprising two or more lasers for providing a laser beam at a single wavelength or absorption wavelength for generating a plurality of *coagulative laser pulses* as recited in the claims of the instant application.

It is clear from the description that the tracking system of Sklar can be used with any number of laser sources. Sklar states that "the therapeutic laser may be a frequency multiplied solid state laser which may be either flash lamp or diode pumped, or an argon, argon pumped dye, excimer, excimer pumped dye, nitrogen, nitrogen pumped dye, or any host of different lasers or combinations thereof." [Sklar, column 16, lines 60-68] The mere recitation of a "combination" of lasers does not suggest or teach the particular configuration of lasers claimed in the instant application. The recitation of a "combination" of lasers is interpretable to mean

independently operable lasers, combination laser and pumping lasers and any other imaginable “combination.”

5 Dew teaches a laser healing method to effect wound closure and reconstruction of biological tissue. Optical energy is applied to produce thermal heating of biological tissue to a degree suitable for denaturing the tissue proteins such that the collagenous elements of the tissue form a biological glue to seal and reconstruct the tissue being heated. [Dew, Abstract] The system of Dew includes a laser 20. Dew teaches a marker laser 30 which is coaligned with the infrared beam of the laser 20. Further, Dew teaches that an auxiliary source of optical energy 50 can be incorporated into the apparatus to emit radiation having a wavelength which is intensely absorbed by biological tissue. Dew does not teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam at a single wave length or absorption wavelength for generating a plurality of coagulative laser pulses as recited in the claims of the instant application.

15 Belkin teaches a method for welding ocular tissues to each other using a carbon dioxide laser. [Belkin, col. 2, lines 35-44] Belkin does not teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam and a laser control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses.

20 Anderson teaches a scheme for confining thermally mediated radiation damage to chosen pigmented targets. [Anderson, p. 524] The technique relies on selective absorption of a brief radiation pulse to generate and confine heat at certain pigmented targets. [Anderson, p. 524] Anderson does not teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam and a laser control system coupled for controlling the laser source for generating a plurality of *coagulative* laser pulses.

25 Accordingly, neither Sklar, Dew, Belkin, Anderson nor their combination teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam at a single wave length or a single predetermined absorption wavelength and a laser control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses.

30 The independent Claim 1 is directed to a medical laser delivery apparatus for delivering one or more pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue comprising a laser source for

generating a series of one or more non-ablative pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode. Claim 1 has been amended to recite that the laser source comprises two or more lasers which are combined into a single laser wavelength output to provide the one or more *non-ablative* pulses. As discussed above, neither Sklar, Dew, Belkin, Anderson nor their combination teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam and a laser control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses with a single laser wavelength output. For at least these reasons, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination.

Claims 2, 3 and 6-8 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 2, 3 and 6-8 are all also allowable as being dependent upon an allowable base Claim.

The independent Claim 11 is directed to a medical laser comprising a laser source having two or more lasers which are combined for generating a laser beam having a predetermined absorption wavelength, wherein the absorption wavelength forms a predetermined coagulation depth in response to an ablative laser pulse; and a laser control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses, such that each such coagulative laser pulse is delivered in sequence to a target area to form a coagulation region deeper than the predetermined coagulation depth. As discussed above, neither Sklar, Dew, Belkin, Anderson nor their combination teach a medical laser with a laser source with two or more lasers which are combined for generating a laser beam having a predetermined absorption wavelength and a laser control system coupled for controlling the laser source for generating a plurality of *coagulative laser pulses*. For at least these reasons, the independent Claim 11 is therefore allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination.

Claims 12-14 are all dependent on the independent Claim 11. As described above, the independent Claim 11 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 12-14 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 17 is directed to a medical laser delivery apparatus for treating an area of tissue. The medical laser delivery apparatus comprises a laser source with two or more lasers which are combined into a single laser wavelength output by a combining apparatus for generating a series of one or more laser pulses each having a strength and a duration. Claim 17 further includes a control system is coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue. As discussed above, neither Sklar, Dew, Belkin, Anderson nor their combination teach a medical laser with a laser source with two or more lasers which are combined into a single laser and a control system coupled for controlling the laser source for generating a plurality of coagulative laser pulses. For at least these reasons, the independent Claim 17 is therefore allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination.

Claims 18 and 19 are both dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 18 and 19 are both also allowable as being dependent upon an allowable base Claim.

Within the Office Action, Claims 4, 5, 9, 10 and 20-24 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Sklar in combination with Dew, Anderson, Belkin and further in view of U.S. Patent No. 5,938,657 to Assa et al. (hereinafter "Assa"). Assa teaches an apparatus for delivering energy within continuous outline. Claims 4, 5, 9 and 10 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 4, 5, 9 and 10 are all also allowable as being dependent upon an allowable base Claim.

Claims 20-24 are all dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 20-24 are all also allowable as being dependent upon an allowable base claim.

For the reasons given above, Applicants respectfully submit that the claims are in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at (650) 833-0160 to discuss the same so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,
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